

ID01065Q  
Application for PTA  
February 27, 2006

Express Mail Label: EV 533190439 US



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No. : 09/655,667 Confirmation No.: 8973  
Applicants : Karen L. Briegs et al.  
Filed : September 6, 2000  
For: : CLINICAL TRIAL MANAGEMENT SYSTEM  
TC/AU : 3626  
Examiner : Natalie Pass  
Docket No. : ID01065Q  
Customer No. : 24265

Mail Stop: ISSUE FEE  
~~Commissioner~~ for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT**  
**UNDER 37 C.F.R. § 1.705**

Sir:

Applicants request reconsideration of the patent term adjustment of 854 days indicated in the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b), which was attached to the October 6, 2005 Notice of Allowance in the above-identified application. Applicants calculate the term adjustment to be **931 days**.

In accordance with 37 C.F.R. § 1.702, the above-identified application was filed after May 29, 2000 and, therefore, is eligible for patent term adjustment under 35 U.S.C. § 154(b).

The issue fee is being paid concurrently herewith. Thus, this request for reconsideration is filed no later than payment of the issue fee, in accordance with 37 C.F.R. § 1.705(b).

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Applicants have provided for payment of the fee set forth in 37 C.F.R. § 1.18(e), as required by 37 C.F.R. § 1.705(b)(1).

The statement of facts regarding the correct patent term adjustment, as required by 37 C.F.R. § 1.705(b)(2), is as follows:

- (i) Applicants filed the above-identified application on September 6, 2000.
- (ii) The Patent and Trademark Office (Office) mailed a Notice to File Missing Parts on October 18, 2000. Applicants responded to the Notice to File Missing Parts on January 22, 2001. Thus, Applicants failed to reply to the Notice to File Missing Parts within three months after its mailing date, as required by 37 C.F.R. § 1.704 (b), resulting in **4 debit days**.
- (iii) The Office mailed a Restriction Requirement on February 7, 2003. Therefore, the Office failed to mail a notification under 35 U.S.C. § 132 or notice of allowance not later than fourteen months after the application filing date, as required by 37 C.F.R. § 1.702(a)(1), resulting in **458 credit days** [37 C.F.R. § 1.703(a)(1)].
- (iv) Applicants filed a response to the Restriction Requirement on March 17, 2003.
- (v) The Office mailed a Non-final Rejection on June 6, 2003. Applicants filed a response to the non-final rejection on September 8, 2003. Thus, applicants failed to reply to the rejection within three months after the rejection mailing date, as required by 37 C.F.R. § 1.704 (b), resulting in **2 debit days**. Applicants filed a Supplemental Reply on November 13, 2003, which reply was not expressly requested by the Examiner, resulting in an additional **66 debit days**.
- (vi) The Office mailed a Final Rejection on February 6, 2004. Thus, the Office failed to respond to a reply under 35 U.S.C. § 132 not later than four months after the date on which the reply was filed, as required by

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37 C.F.R. § 1.702(a)(2), which results in **29 credit days** [37 C.F.R. § 1.703(a)(2)].

- (vii) In response to the Final Rejection, Applicants filed a Notice of Appeal and an Appeal Brief on March 29, 2004. The Board of Patent Appeals and Interferences (BPAI) reversed the Final Rejection in a final decision issued on June 6, 2005. Thus, under 37 C.F.R. § 1.702(e) and 1.703(e), Applicants are entitled to **435 credit days**.
- (viii) The Office mailed a Notice of Allowance on November 25, 2005. Thus, the Office failed to act on an application appealed under 35 U.S.C. § 134 not later than four months after the date of the BPAI decision as required under 37 C.F.R. § 1.702(a)(3), resulting in **50 credit days** (37 C.F.R. § 1.703(a)(5)).
- (ix) Since the issue fee is being paid on the date that is three months after the mailing date of the Notice of Allowance, the projected issue date is June 5, 2006, which will be **1003 days** after September 6, 2003. Thus, the Office failed to issue a patent within three years after the date on which the application was filed as required under 37 C.F.R. § 1.702(b). Since a total of **435 days** was consumed by review by the Board of Patent Appeals and Interferences [37 C.F.R. § 1.702(b)], Applicants are due **568 credit days**. If the application issues earlier or later than June 5, 2006, then the exact number of credit days will be fewer or greater, respectively.
- (x) The sum of the credit-day period for a successful appeal (435 days) and the longest of the overlapping credit-day periods discussed above (568 days) is **1003 credit days**. The sum of the three debit-day periods discussed above is **72 days**. Accordingly, under 37 C.F.R. § 1.703(f), the patent term adjustment is 1003 days less 72 days, totaling **931 days**.
- (xi) The above facts are presented in the attached report of a patent term analysis performed by a commercially available software program.

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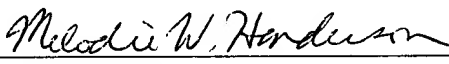
(xii) The patent is not subject to a terminal disclaimer [37 C.F.R. § 1.705(b)(2)(iii)].

(xiii) There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination as set forth in 37 C.F.R. § 1.704 [37 C.F.R. § 1.705(b)(2)(iv)].

A Fee Transmittal Form is enclosed herewith authorizing the fee of \$200.00 as set forth in 37 C.F.R. § 1.18(e) and any additional fees to be charged to our Deposit Account. Any refund in fees may be credited to the same Deposit Account.

February 27, 2006  
Schering-Plough Corporation  
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Respectfully submitted,

  
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FEB 27 2006

PTO/SB/17 (12-04)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Effective on 12/08/2004.

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 2646)

**FEE TRANSMITTAL**  
**For FY 2005****Complete if Known**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$ ) 200.00

Application Number 09/655667

Filing Date 09/06/2000

First Named Inventor BRIEGS, Karen L

Examiner Name Pass, Natalie

Art Unit 3626

Attorney Docket No. ID01065Q

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 19-0365 Deposit Account Name: Schering-Plough Corporation

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17☒ Credit any overpayments**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP =	x	=				
HP = highest number of total claims paid for, if greater than 20						
Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)			
- 3 or HP =	x	=				
HP = highest number of independent claims paid for, if greater than 3						

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x	=	

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other: Fee for application for Patent Term Adjustment Under 37 CFR 1.705

**Fees Paid (\$)**

200.00

**SUBMITTED BY**

Signature	Melodie W. Henderson	Registration No. (Attorney/Agent) 37,848	Telephone 908-298-7482
Name (Print/Type)	Melodie W. Henderson		Date Feb. 27, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.